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EXAMINER

CROW, ROBERT THOMAS

ART UNIT	PAPER NUMBER
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1634

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,001	Applicant(s) GUMBRECHT ET AL.	
	Examiner Robert T. Crow	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7, 9-27 and 29-31 is/are pending in the application.
- 4a) Of the above claim(s) 16-27 and 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7 and 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

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FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 18 September 2007 in which claims 1-4, 7, 9-11, and 14 were amended, claims 5-6, 8, and 28 were canceled, and no new claims were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

Claims 1-4, 7, and 9-15 are under prosecution.

Information Disclosure Statement

2. The Information Disclosure Statement filed 18 September 2004⁷ is acknowledged. However, only the Abstract of Document DE 102 33 212 B4 is being considered because an English language translation of the remainder of the document has not been provided.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-4, 7, and 9-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 7, and 9-15 are indefinite in claim 1 and claim 2, each of which recites "the spot arrays" in line 7 of independent claim 1 and in line 3 of claim 2. The plural recitation "the spot arrays"

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lacks antecedent basis in the singular recitation "a spot array" in line 5 of claim 1. It is suggested the claims be amended to reflect proper antecedent basis.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 4, 9-11, and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chateau (U.S. Patent No. 4,071,315, issued 31 January 1978) in view of Chen et al (U.S. Patent Application Publication No. US 2001/0051714 A1, published 13 December 2001) in view of Gordon et al (U.S. Patent Application Publication No. US 2001/0036641 A1, published 1 November 2001).

Regarding claims 1 and 12, Chateau teaches a method for performing a high throughput analysis. In a single exemplary embodiment, Chateau teaches a method comprising a biochip with a multiplicity of successive areas 13 (column 5, lines 10-30). Chateau also teaches the tape has spots on the biochip in the form of antibodies pre-attached to the tape (column 3, lines 50-57) having several antigen specimens

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(Abstract) are placed side by side along the tape (column 2, lines 57-66) in each area. Thus, a side by side placement of several antigens along the antibody tape is a biochip comprising a plurality of spots (i.e., a spot array) in the form of the two side by side deposits of antigens, and the biochips are on the tape, which is the instantly claimed carrier. Chateau further teaches the biochips are situated in a carrier in the form of a longitudinal tape that allows continuous analysis of the plurality of samples (Abstract). A sample liquid, in the form of serum containing antibodies to the antigen spots of the biochips, is then deposited on the biochips ((column 5, line 60- column 6, line 10). Chateau teaches flushing liquids are applied from above the carrier onto the spots of the spot arrays located on the carrier; namely, the tape is rinsed in rinsing station 25 from above (Figure 1 and column 6, lines 10-25). Chateau also teaches analyzing the samples of measurement liquid, wherein applying and analyzing are effected simultaneously at different spots; namely, depositing and processing (i.e., analyzing) of several side by side specimens (i.e., different spots of the spot arrays) occurs simultaneously with the recording (i.e., measuring) of information regarding each specimen and the treatment that is given to each specimen (column 2, lines 57-67). The carrier is moved to permit a continuous measurement at a speed determined by a movement cycle of the carrier; namely, depositing stations are multiplied so that multiple simultaneous analyses are carried out by the machine, wherein the tape is progressed by a number of areas as part of the depositing and analysis (column 5, lines 10-30). The progression of the tape is a movement cycle.

Chateau does not teach electrical measurements are carried out from below the carrier with the aid of contact elements; i.e., a tape having electrical contact elements (claim 1) so that measurements are with biochips that are electrically readable (i.e., claim 12). Thus, Chateau teaches a base method that differs from the instantly claimed method because Chateau does not teach electrical measurements are carried out from below the carrier with the aid of contact elements.

However, Chen et al teach a substrate in the form of a flexible tape (Abstract) having spots of probes thereon (paragraph 0017), wherein the substrate comprises a metallic electrode layer (paragraph

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0119). The metallic electrode layer is a contact element, and Chen et al teach the substrate has the added advantage of allowing the driving of probes (i.e., measurement spots) onto the tape (paragraph 0119), which aids in the synthesis of the measurement spots. Thus, Chen et al teaches the known technique of using a carrier having electrical contact elements.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method comprising a carrier as taught by Chateau with the carrier having contact elements of Chen et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a method having the added advantage of allowing the driving of measurement spots of probes onto the tape, thereby aiding in the synthesis of the carrier, as explicitly taught by Chen et al (paragraph 0119). In addition, it would have been obvious to the ordinary artisan that the known technique of using the contact elements of Chen et al could have been applied to the method of Chateau with predictable results because the contact elements of Chen et al predictably result in a carrier useful for biomolecular binding assays.

Neither Chateau nor Chen et al teach electrical measurements are carried out from below the carrier with the aid of contact elements; i.e., so that measurements are with biochips that are electrically readable (i.e., claims 1 and 12). Thus, Chateau in view of Chen et al teach a base method that differs from the instantly claimed method because Chateau in view of Chen et al does not teach electrical measurements are carried out from below the carrier.

However, Gordon et al teach electrically readable biochips wherein spots of oligonucleotides are attached to an uppermost layer of an electrode (Figures 1-2 and paragraph 0091), wherein electrical contacts for measurements in the form of data and address buses 126, 128, and 130, which are below the carrier (Figures 1 and 2 and paragraphs 0085 and 0131), and which have the added advantage of allowing selective chemical activity at specific electrodes on the chip (paragraph 0040). Thus, Gordon et al teach

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the known technique of using electrically addressable biochips (i.e., claim 12) having electrical contact elements for measurements to be carried out from below the carrier (i.e., claim 1).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method comprising a carrier having an electrode as taught by Chateau in view of Chen et al with the electrically readable biochips (i.e., claim 12) having contact elements for measurements that are carried out from below the carrier (i.e., claim 1) as taught by Gordon et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a method having the added advantage of allowing selective chemical activity at specific electrodes on the chip as explicitly taught by Gordon et al (paragraph 0040). In addition, it would have been obvious to the ordinary artisan that the known technique of using the electrically addressable biochips having electrical contact elements for measurements to be carried out from below the carrier of Gordon et al could have been applied to the method of Chateau in view of Chen et al with predictable results because the biochips and elements of Gordon et al predictably result in a carrier useful having individually addressable electrodes.

Regarding claim 4, the method of claim 1 is discussed above. Chateau also teaches temperature regulation is interposed between the applying and analyzing of the sample liquid; namely, the tape proceeds through incubation enclosure 31 after depositing the measurement liquid by needle 28 but before the tape reaches result reading station 36 (Figure 2). The incubation enclosure 31 is identical to incubation enclosure 20, which controls the temperature (column 5, lines 59-60).

Regarding claim 9, the method of claim 1 is discussed above. Chateau further teaches the carrier is made of a flat material; namely, a flat tape (Figures 1 and 2 and column 4, lines 28-39).

Regarding claim 10, the method of claim 9 is discussed above. Chateau teaches a band-shaped carrier made of flexible material is used; namely, a flexible tape (Figures 1 and 2 and column 4, lines 28-39), which is band-shaped.

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Regarding claim 11, the method of claim 10 is discussed above. Chateau also teaches the band-shaped carrier is unwound from the roll in cartridge 2 (Figure 2 and column 4, lines 45-55) and transported through reading station 36, which is an analysis unit (Figure 2 and column 7, lines 33-50).

Regarding claim 13, the method of claim 1 is discussed above. Chateau further teaches the carrier has analysis specific data present; namely, the each spot on the carrier has data relating the specimen and specimen treatment, which is analysis specific data, recorded along the side of the tape next to each spot (column 2, lines 57-66).

Regarding claim 14, the method of claim 1 is discussed above. Chateau teaches heat is supplied or dissipated from the rear side region of the carrier opposite to the array; namely, the tape is heated in enclosure 31 (column 4, lines 59-60 and claim 4). Because the entire enclosure 31 is heated, at least some heat is supplied or dissipated from the rear side region of the tape.

Regarding claim 15, the method of claim 14 is discussed above. Chateau also teaches a rear side region is brought into areal contact with a coolable or heatable body; namely, the tape is heated in enclosure 31 (column 4, lines 59-60 and claim 4). Because the entire enclosure 31 is heated, the air gasses within the enclosure contact the rear of the carrier. The air gasses within the enclosure are a gaseous body that is coolable or heatable.

8. Claims 2-3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chateau (U.S. Patent No. 4,071,315, issued 31 January 1978) in view of Chen et al (U.S. Patent Application Publication No. US 2001/0051714 A1, published 13 December 2001) in view of Gordon et al (U.S. Patent Application Publication No. US 2001/0036641 A1, published 1 November 2001) as applied to claim 1 above, and further in view of Chetverin et al (U.S. Patent No. 6,103,463, issued 15 August 2000).

Regarding claim 2, the method of claim 1 is discussed above in Section 7.

Chateau also teaches temperature regulation and air conditioning is interposed between the applying and analyzing; namely, the tape proceeds through incubation enclosure 31 after depositing the

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measurement liquid by needle 28 but before the tape reaches result reading station 36 (Figure 2). The incubation enclosure 31 is identical to incubation enclosure 20, which controls temperature and humidity (column 5, lines 59-60), thereby interposing temperature and air conditioning on the sample. Chateau further teaches at least one spot array is enclosed by a hollow body in order to create a spatial separation from other spot arrays; namely, the carrier tape is run through enclosure 31 (Figure 2). Because at least one area 13 is held in the enclosure (column 5, lines 59-60 and claim 4), at least one spot array is held therein and is spatially separated from other spot arrays.

While Chateau does not teach the hollow body surrounds the spot array in a sealing fashion with a circumferential wall, Chen et al teach a hollow body in the form of a mostly water-tight capillary is formed by closing a lid (i.e., placing a wall) on a narrow slot on a substrate, which circumferentially encloses at least one spot of the array on the carrier because the founded capillary and lid circumferentially seal the array carrier therein. (Figures 17a-b and paragraph 0160). Chen et al also teach the circumferential wall has the added advantage of allowing improved hybridization efficiency (paragraph 0160). Thus, Chen et al teach the hollow body surrounds the spot array in a sealing fashion with a circumferential wall.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method comprising a carrier and a hollow body as taught by Chateau in view of Chen et al with the circumferentially enclosing wall of Chen et al as taught with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a method having the added advantage of allowing improved hybridization efficiency as explicitly taught by Chen et al (paragraph 0160). In addition, it would have been obvious to the ordinary artisan that the known technique of using the wall of Chen et al could have been applied to the method of Chateau in view of Chen et al in view of Gordon et al with predictable results because the wall of Chen et al predictably results in a carrier useful for hybridization reactions.

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While Chen et al teach the circumferential wall is mostly water tight (paragraph 0160), neither Chateau, Chen et al, or Gordon teach a totally sealed environment.

However, Chetverin et al teach sealing of arrays on a tape (column 14, lines 13-24) with impermeable walls has the added advantage of isolating individual wells (i.e., arrays or spots) from each other (column 10, lines 16-67) which prevents cross contamination of samples from different spots or arrays. Thus, Chetverin et al teach the known technique of using a totally sealed environment.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method comprising a mostly water tight circumferential wall of Chateau in view of Chen et al and Gordon et al with the sealing of Chetverin et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a method having the added advantage of preventing cross contamination of samples from different spots or arrays as a result of the isolation of arrays or spots from each other as explicitly taught by Chetverin et al (column 10, lines 16-67). In addition, it would have been obvious to the ordinary artisan that the known technique of sealing the hollow body of Chetverin et al could have been applied to the method of Chateau in view of Chen et al in view of Gordon et al with predictable results because the seal of Chetverin et al predictably results in a carrier useful for hybridization reactions.

Regarding claim 3, the method of claim 2 is discussed above. Chateau also teaches the air conditioning serves as residence time of the measurement sample on the biochip; namely, the air conditioning in incubation enclosure 31 controls the humidity of the deposited sample (column 4, lines 59-60 and claim 4) for a specific period of time (column 8, lines 15-20).

Regarding claim 7, the method of claim 2 is discussed above. Chateau also teaches the hollow body serves for air conditioning of the gas phase present above a spot array; namely, the spot arrays are the biochips, which are contained in enclosure 31, which is a hollow body. Because hollow body

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enclosure 31 controls the temperature and humidity of the deposited sample (column 4, lines 59-60 and claim 4), the gas phase (i.e., the air) above the spot array is air conditioned.

Response to Arguments

9. Applicant's arguments with respect to the previous rejections of the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments.

Conclusion

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

12. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Jehanne Sitton/
Primary Examiner
11/19/2007

Robert T. Crow
Examiner
Art Unit 1634

